

ZO SKIN HEALTH LEVEL III AGGRESSIVE ANTI-AGING PROGRAM WITH ADVANCED RADICAL NIGHT REPAIR- titanium dioxide and zinc oxide

ZO Skin Health, Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

ZO® SKIN HEALTH

LEVEL III: AGGRESSIVE ANTI-AGING PROGRAM with Advanced Radical Night Repair

Drug Facts

<i>Active ingredients</i>	<i>Purpose</i>
Titanium Dioxide 10.2%	Sunscreen
Zinc Oxide 3.7%	Sunscreen

Uses

- Helps prevent sunburn.
- If used as directed with other sun protection measures (see ***Directions***), decreases the risk of skin cancer and early skin aging caused by the sun.

Warnings

For external use only.

Do not use on damaged or broken skin.

Stop and ask a doctor if rash occurs.

When using this product keep out of eyes. Rinse with water to remove.

Keep out of reach of children. If swallowed, get medical help or contact a poison control center right away.

Directions

- Apply liberally 15 minutes before sun exposure
- Use a water resistant sunscreen if swimming or sweating
- Reapply at least every 2 hours
- Children under 6 months: Ask a doctor
- **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including:
 - Limit time in the sun, especially from 10 a.m.- 2 p.m.
 - Wear long-sleeved shirts, pants, hats and sunglasses.
- Apply to all skin exposed to the sun

Other information

- Protect the product in this container from excessive heat and direct sunlight.
- You may report a serious adverse reaction to:
1 Technology Dr., B123, Irvine, CA 92618

Inactive ingredients

Cyclopentasiloxane, Cyclotetrasiloxane, Dimethicone/Vinyl Dimethicone Crosspolymer, Methyl Methacrylate/Glycol Dimethacrylate Crosspolymer, Dimethicone Crosspolymer, Melanin, Tribehenin, Calcium Behenate, Sorbitan Isostearate, Dimethiconol, Alumina, Laureth-23, Methicone, PEG-10 Dimethicone, PPG-2 Myristyl Ether Propionate, Propylparaben, Methylparaben, Myristoyl Pentapeptide-8, Iron Oxide (CI 77492).

DIST BY

ZO Skin Health, Inc. Irvine, CA 92618

PRINCIPAL DISPLAY PANEL - Kit Carton

ZO[®] SKIN HEALTH
BY ZEIN OBAGI, MD

LEVEL III: AGGRESSIVE ANTI-AGING PROGRAM

with Advanced Radical Night Repair

NDC 42851-154-01

beverly hills

Comprehensive Skin Health Solutions
from Zein Obagi, MD



ZO[®] SKIN HEALTH
BY ZEIN OBAGI, MD

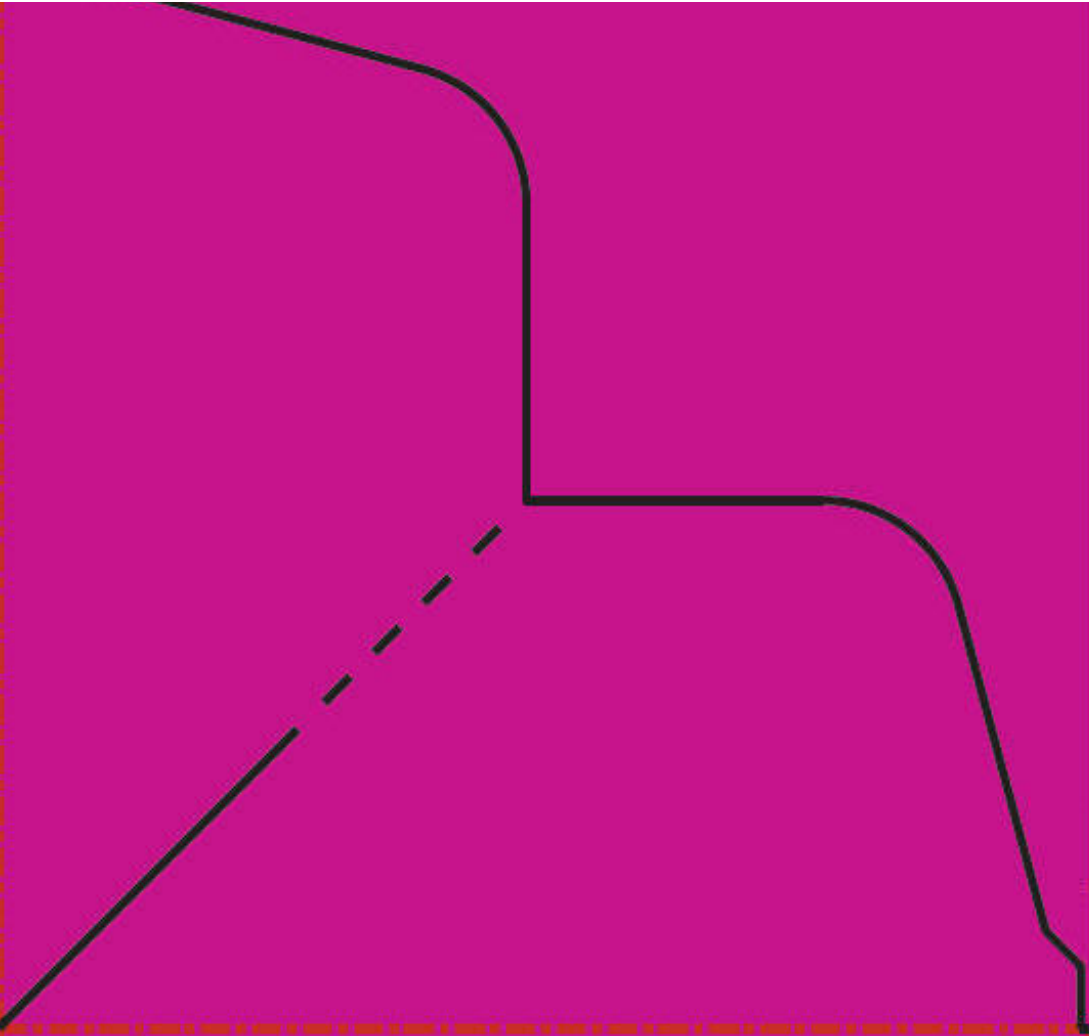


LEVEL III: AGGRESSIVE ANTI-AGING PROGRAM

with Advanced Radical Night Repair

NDC 4285 1-154-01

beverly hills



The best treatment for aging skin is to replace damaged skin cells with new, healthy ones. Deeper lines and wrinkles require higher levels of active ingredients, and that's what Zein Obagi, MD does best. His acclaimed Ossential® Advanced Radical Night Repair contains an ultra-high concentration of retinol, the most potent treatment for environmental and intrinsic (natural) skin aging.

- Helps reduce deeper lines and wrinkles
- Helps maintain the results achieved with lasers or medical treatments
- Aids in restoring skin elasticity
- Minimizes hyperpigmentation and "age spots"
- Creates more even skin tone
- Aids in strengthening the skin by boosting collagen production

Apply a small amount to damp face and neck. Massage skin in a circular motion; adding water as necessary. Rinse thoroughly. Use at least twice a week.

INGREDIENTS PEG-8, Sodium Bicarbonate, Ethoxydiglycol, Magnesium Oxide, Glycerin, Oleth-20, Glyceryl Stearate, Trihydroxystearin, PEG-100 Stearate, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, Retinyl Palmitate, Ascorbyl Palmitate, Caprylic/Capric Triglyceride, Linoleic Acid, Glycine Soja Sterols, Phospholipids, Melaleuca Alternifolia Leaf Oil, Propylparaben, Stearyl Glycerylacetate, Parfum, Green 6 (CI 61585).

ESSENTIAL® DAILY POWER DEFENSE

30 mL / 1 Fl. Oz.

Following cleansing, apply 2-3 pumps on face and neck every morning. Massaging skin increases absorption, penetration and stimulation. Follow with Occlipse® Sunscreen + Primer Broad-Spectrum SPF 30.

INGREDIENTS Water (Aqua), Cetearyl Isononanoate, Cyclopentasiloxane, Cyclohexasiloxane, Pentylene Glycol, Retinol, Lecithin, Polysorbate 20, Glycerin, Steareth-20, Cetearyl Alcohol, Jojoba Esters, Retinyl Palmitate, Tocopheryl Acetate, Beta-Glucan, Lactose, Citrus Aurantium Dulcis (Orange Peel Oil), Citrus Nobilis (Mandarin Orange) Peel Oil, Citrus Limon (Lemon) Peel Oil, Citrus Reticulata (Tangerine) Peel, Mentha Piperita (Peppermint) Oil, Mimosa Teniflora Bark Extract, Arabidopsis Thaliana Extract, Micrococcus Lysate, C14-22 Alcohols, Safflower Oil/Palm Oil Aminopropanedil Esters, Cetearyl Glucoside, C12-20 Alkyl Glucoside, Cellulose, Butylene Glycol, Palmitoyl Oligopeptide, Palmitoyl Tetrapeptide-7, Sodium Hydroxide, Carbomer, Hydroxypropyl Methylcellulose, Hexylene Glycol, Disodium EDTA, Caprylyl Glycol, Ethylhexylglycerin, Phenoxyethanol, Limonene, Ultramarines (CI 77007), Ext. Violet 2 (CI 60730).

ESSENTIAL® ADVANCED RADICAL NIGHT REPAIR

30 mL / 1 Fl. Oz.

Due to the concentration of retinol, this is a very potent product. Initially some dryness, irritation and peeling are normal. These symptoms typically develop 3-7 days following the first application and indicate skin cells are awakening, and damaged skin is being shed.

If you are not currently using retinol, begin gradually. Following cleansing, apply 2-3 pumps twice a week in the evening, 30 minutes before retiring. Increase frequency as tolerated. Do not apply anything on top of Advanced Radical Night Repair.

INGREDIENTS Cyclopentasiloxane, Dimethicone Crosspolymer, Dimethicone, Prunus Amygdalus Dulcis Oil, Glycerin, Polysorbate 20, Water (Aqua), Retinol, Cyclohexasiloxane, Diisopropyl Adipate, Plukenetia Volubilis Seed Oil, Oleyl Alcohol, Phenoxyethanol, Tocopheryl Acetate, Helianthus Annuus Seed Oil, BHT, Chlorphenesin, Leontopodium Alpinum Meristem Cell Culture, Marrubium Vulgare Meristem Cell Culture, Zanthoxylum Bungeanum Fruit Extract, Sodium Sulfite, Caprylyl Glycol, Ascorbyl Palmitate, Gluconolactone, BHA, Rosmarinus Officinalis Leaf Extract, Sodium Benzoate, Lecithin, Xanthan Gum, Parfum, Tocopherol, Ascorbic Acid, Zea Mays Oil, Beta-Carotene.

BROAD-SPECTRUM SPF 30 UVA/UVB PROTECTION
15 mL / 0.5 Fl. Oz. (NDC 42851-051-01)

Drug Facts

Active ingredients

Titanium Dioxide 10.2%
Zinc Oxide 3.7%

Purpose

Sunscreen
Sunscreen

Uses

- Helps prevent sunburn.
- If used as directed with other sun protection measures (see *Directions*), decreases the risk of skin cancer and early skin aging caused by the sun.

Warnings

For external use only.

Do not use on damaged or broken skin.

Stop and ask a doctor if rash occurs.

When using this product keep out of eyes. Rinse with water to remove.

Keep out of reach of children. If swallowed, get medical help or contact a poison control center right away.

Directions

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- Use a water resistant sunscreen if swimming or sweating
- Reapply at least every 2 hours
- Children under 6 months: Ask a doctor
- Sun Protection Measures. Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including:
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Other information

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Inactive ingredients

Cyclopentasiloxane, Cyclohexasiloxane, Dimethicone, Vinyl Dimethicone Crosspolymer, Methyl Methacrylate/Glycol Dimethacrylate Crosspolymer, Dimethicone Crosspolymer, Melanin, Tribehenin, Calcium Behenate, Sorbitan Isostearate, Dimethiconol, Alumina, Laureth-23, Methicone, PEG-10 Dimethicone, PPG-2 Myristyl Ether Propionate, Propylparaben, Methylparaben, Myristyl Pentapeptide-8, Iron Oxide (CI 77492).





ZO® SKIN HEALTH PROGRAMS

LEVEL I: DAILY SKINCARE PROGRAM

LITTLE or NO apparent signs of chronological or photo-aging.

Our Daily Skincare Program is an everyday skincare regimen to maintain healthy looking skin. These basic tools have retinol and specialized enzymes to encourage cellular activity, repair damaged cells and protect against future damage.

LEVEL II: ANTI-AGING PROGRAM

EARLY signs of intrinsic aging—fine lines, uneven skin tone and loss of firmness.

This moderately aggressive program, with highly advanced anti-aging skincare tools, helps to repair and prevent damaged skin. Active ingredients, such as growth factors, retinol and specific enzymes assist in improving the cellular repair function and restore the appearance of youthful, healthy skin.

LEVEL III: AGGRESSIVE ANTI-AGING PROGRAM

DEFINITE signs of aging skin—wrinkles, brown patches, loose skin, large pores and obvious sun damage.

This aggressive program, using high concentrations of retinol, is for anyone with

skin aging concerns. Using these tools can help correct and rejuvenate the skin, revealing radical improvement of wrinkles, fine lines, brown patches, rough texture and sagging skin.

DIST BY

ZO Skin Health, Inc. Irvine, CA 92618

MADE IN USA 093602

ZO® is a registered trademark of
ZO Skin Health, Inc.

www.zoskinhealth.com



**ZO SKIN HEALTH LEVEL III AGGRESSIVE ANTI-AGING PROGRAM WITH
ADVANCED RADICAL NIGHT REPAIR**

titanium dioxide and zinc oxide kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42851-154
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42851-154-01	1 in 1 CARTON		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 JAR	16.2 g
Part 2	1 TUBE	40 mL
Part 3	1 JAR	50 mL
Part 4	1 BOTTLE, PUMP	30 mL
Part 5	1 TUBE, WITH APPLICATOR	30 mL
Part 6	1 BOTTLE, PUMP	15 mL

Part 1 of 6

OFFECTS EXFOLIATING POLISH ANTI-AGING FORMULA

cleansing (cold creams, cleansing lotions, liquids, and pads) cream

Product Information

Route of Administration	TOPICAL
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Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
INGR	SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
INGR	DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A1I8X02B)	
INGR	MAGNESIUM OXIDE (UNII: 3A3U0GI71G)	
INGR	GLYCERIN (UNII: PDC6A3C0OX)	
INGR	Oleth-20 (UNII: YTH167I2AG)	
INGR	GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
INGR	TRIHYDROXYSTEARIN (UNII: 06YD7896S3)	
INGR	PEG-100 Stearate (UNII: YD01N1999R)	
INGR	TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
INGR	.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
INGR	VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
INGR	ASCORBYL PALMITATE (UNII: QN83US2B0N)	
INGR	MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
INGR	LINOLEIC ACID (UNII: 9KJL21T0QJ)	
INGR	SOY STEROL (UNII: PL360EPO9J)	
INGR	OMEGA-3 FATTY ACIDS (UNII: 71M78END5S)	
INGR	TEA TREE OIL (UNII: VIF565UC2G)	

INGR	PROPYLPARABEN (UNII: Z8IX2SC1OH)	
INGR	STEARYL GLYCYRRHETINATE (UNII: 3YYE6VJS0P)	
INGR	D&C GREEN NO. 6 (UNII: 4QP5U84YF7)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		16.2 g in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
COSMETIC		01/11/2012	

Part 2 of 6

OFFETS HYDRATING CLEANSER NORMAL TO DRY SKIN ANTI-AGING FORMULA

cleansing (cold creams, cleansing lotions, liquids, and pads) lotion

Product Information

Route of Administration	TOPICAL
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Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	WATER (UNII: 059QF0K00R)	
INGR	SODIUM METHYL CO COYL TAURATE (UNII: JVL98CG53G)	
INGR	SODIUM CO COYL ISETHIONATE (UNII: 518XTE8493)	
INGR	DISODIUM CO CO AMPHODIACETATE (UNII: 18L9G3U51M)	
INGR	GLYCERIN (UNII: PDC6A3C0OX)	
INGR	SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
INGR	UREA (UNII: 8W8T17847W)	
INGR	TREHALOSE (UNII: B8WCK70T7I)	
INGR	HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
INGR	GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
INGR	PEG-100 STEARATE (UNII: YD01N1999R)	
INGR	CETYL ALCOHOL (UNII: 936JST6JCN)	
INGR	GLYCOL DISTEARATE (UNII: 13W7MDN21W)	
INGR	STEARIC ACID (UNII: 4ELV7Z65AP)	
INGR	ALLANTOIN (UNII: 344S277G0Z)	
INGR	PANTHENOL (UNII: WV9CM0O67Z)	
INGR	SODIUM HYDROXIDE (UNII: 55X04QC32I)	
INGR	METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
INGR	METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	

INGR	D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
INGR	FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		40 mL in 1 TUBE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
COSMETIC		01/11/2012	

Part 3 of 6

OMMERSE RENEWAL ANTI-AGING FORMULA
cleansing (cold creams, cleansing lotions, liquids, and pads) cream

Product Information	
Route of Administration	TOPICAL

Other Ingredients		
Ingredient Kind	Ingredient Name	Quantity
INGR	WATER (UNII: 059QF0KO0R)	
INGR	ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
INGR	ISOCETYL STEARATE (UNII: 3RJ7186O9W)	
INGR	GLYCERIN (UNII: PDC6A3C0OX)	
INGR	CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
INGR	Polysorbate 60 (UNII: CAL22UVI4M)	
INGR	EGG PHOSPHOLIPIDS (UNII: 1Z74184RGV)	
INGR	JOJOBA BUTTER (UNII: XIA46H803R)	
INGR	SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
INGR	OAT (UNII: Z6J799EAJK)	
INGR	RETINOL (UNII: G2SH0XKK91)	
INGR	C10-18 TRIGLYCERIDES (UNII: 43AGM4PHPI)	
INGR	BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
INGR	PHENOXYETHANOL (UNII: HIE492ZZ3T)	
INGR	ECTOINE (UNII: 7GXZ3858RY)	
INGR	STEARETH-21 (UNII: 53J3F32P58)	
INGR	COCOS NUCIFERA WHOLE (UNII: 245J88W96L)	
INGR	GARDENIA TAITENSIS FLOWER (UNII: T0OCU8201Y)	
INGR	DIMETHICONE (UNII: 92RU3N3Y1O)	
INGR	LAURETH-23 (UNII: N72LMW566G)	
INGR	TOCOPHEROL (UNII: R0ZB2556P8)	

INGR	MAGNESIUM ASCORBYL PHOSPHATE (UNII: 0R822556M5)	
INGR	CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
INGR	STEARETH-2 (UNII: V56DFE46J5)	
INGR	CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
INGR	SODIUM HYDROXIDE (UNII: 55X04QC32I)	
INGR	EDETATE SODIUM (UNII: MP1J8420LU)	
INGR	ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
INGR	SOYBEAN OIL (UNII: 241ATL177A)	
INGR	HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
INGR	EPILOBIUM ANGUSTIFOLIUM FLOWERING TOP (UNII: 08H094218D)	
INGR	HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
INGR	HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)	
INGR	SOY STEROL (UNII: PL360EPO9J)	
INGR	UBIDECARENONE (UNII: EJ27X76M46)	
INGR	Sodium Chloride (UNII: 451W47IQ8X)	
INGR	Sodium Metabisulfite (UNII: 4VON5FNS3C)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		50 mL in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
COSMETIC		01/11/2012	

Part 4 of 6

OSSENTIAL DAILY POWER DEFENSE ANTI-AGING FORMULA

cleansing (cold creams, cleansing lotions, liquids, and pads) lotion

Product Information

Route of Administration	TOPICAL
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Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	WATER (UNII: 059QF0KO0R)	
INGR	CETEARYL ISONONANOATE (UNII: P5O01U99NI)	
INGR	CYCLOMETHICONE 5 (UNII: 0TH5PC10R)	
INGR	CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
INGR	PENTYLENE GLYCOL (UNII: 50C1307PZG)	
INGR	RETINOL (UNII: G2SH0XKK91)	

INGR	EGG PHOSPHOLIPIDS (UNII: 1Z74184RGV)	
INGR	POLYSORBATE 20 (UNII: 7T1F30V5YH)	
INGR	GLYCERIN (UNII: PDC6A3C0OX)	
INGR	STEARETH-20 (UNII: L0Q8IK9E08)	
INGR	CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
INGR	JOJOBA BUTTER (UNII: XIA46H803R)	
INGR	VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
INGR	.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
INGR	CURDLAN (UNII: 6930DL209R)	
INGR	LACTOSE (UNII: J2B2A4N98G)	
INGR	ORANGE OIL (UNII: AKN3KSD11B)	
INGR	MANDARIN OIL (UNII: NJO720F72R)	
INGR	LEMON OIL (UNII: I9GRO824LL)	
INGR	PEPPERMINT OIL (UNII: AV092KU4JH)	
INGR	MIMOSA TENUIFLORA BARK (UNII: 515MQE449I)	
INGR	ARABIDOPSIS THALIANA (UNII: AI3L60HQ81)	
INGR	C14-22 ALCOHOLS (UNII: B1K89384RJ)	
INGR	CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
INGR	C12-20 ALKYL GLUCOSIDE (UNII: K67N5Z1RUA)	
INGR	POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
INGR	BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
INGR	PALMITOYL OLIGOPEPTIDE (UNII: HO4ZT5S86C)	
INGR	PALMITOYL TETRAPEPTIDE-7 (UNII: Q41S464P1R)	
INGR	SODIUM HYDROXIDE (UNII: 55X04QC32I)	
INGR	CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
INGR	HYPROMELLOSES (UNII: 3NXW29V3WO)	
INGR	HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
INGR	EDETATE DISODIUM (UNII: 7FLD91C86K)	
INGR	CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
INGR	ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
INGR	PHENOXYETHANOL (UNII: HIE492ZZ3T)	
INGR	LIMONENE, (+/-)- (UNII: 9MC3I34447)	
INGR	ULTRAMARINE BLUE (UNII: I39WR998BI)	
INGR	EXT. D&C VIOLET NO. 2 (UNII: G5UX3K0728)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		30 mL in 1 BOTTLE, PUMP		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
COSMETIC		01/11/2012	

OSSENTIAL ADVANCED RADICAL NIGHT REPAIR ANTI-AGING FORMULA

cleansing (cold creams, cleansing lotions, liquids, and pads) lotion

Product Information

Route of Administration TOPICAL

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
INGR	DIMETHICONE (UNII: 92RU3N3Y1O)	
INGR	ALMOND OIL (UNII: 66YXD4DKO9)	
INGR	GLYCERIN (UNII: PDC6A3C0OX)	
INGR	POLYSORBATE 20 (UNII: 7T1F30V5YH)	
INGR	WATER (UNII: 059QF0KO0R)	
INGR	RETINOL (UNII: G2SH0XKK91)	
INGR	CYCLOMETHICONE 4 (UNII: CZ227117JE)	
INGR	DIISOPROPYL ADIPATE (UNII: P7E6YFV72X)	
INGR	PLUKENETIA VOLUBILIS SEED OIL (UNII: 8ED72Z8J1Z)	
INGR	OLEYL ALCOHOL (UNII: 172F2WN8DV)	
INGR	PHENOXYETHANOL (UNII: HE492ZZ3T)	
INGR	.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
INGR	SUNFLOWER OIL (UNII: 3W1JG795YI)	
INGR	BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
INGR	CHLORPHENESIN (UNII: I670DAL4SZ)	
INGR	ZANTHOXYLUM BUNGEANUM FRUIT (UNII: 3CIP16A418)	
INGR	SODIUM SULFITE (UNII: VTK01UQK3G)	
INGR	CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
INGR	ASCORBYL PALMITATE (UNII: QN83US2B0N)	
INGR	GLUCONOLACTONE (UNII: WQ29KQ9POT)	
INGR	BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
INGR	ROSEMARY (UNII: IJ67X351P9)	
INGR	SODIUM BENZOATE (UNII: OJ245FE5EU)	
INGR	EGG PHOSPHOLIPIDS (UNII: 1Z74184RGV)	
INGR	XANTHAN GUM (UNII: TTV12P4NEE)	
INGR	TOCOPHEROL (UNII: R0ZB2556P8)	
INGR	ASCORBIC ACID (UNII: PQ6CK8PD0R)	
INGR	CORN OIL (UNII: 8470G57WFM)	
INGR	.BETA.-CAROTENE (UNII: 01YAE03M7J)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		30 mL in 1 TUBE, WITH APPLICATOR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
COSMETIC		01/11/2012	

Part 6 of 6

OCLIPSE SUNSCREEN PLUS PRIMER BROAD-SPECTRUM SPF 30 UVA/UVB PROTECTION

titanium dioxide and zinc oxide lotion

Product Information

Item Code (Source)	NDC:42851-051
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	102 mg in 1 mL
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	37 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
CYCLOMETHICONE 4 (UNII: CZ227117JE)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
METHYL METHACRYLATE/GLYCOL DIMETHACRYLATE CROSSPOLYMER (UNII: EG97988M5Q)	
TRIBEHENIN (UNII: 8OC9U7TQZ0)	
CALCIUM BEHENATE (UNII: J5VFA9V6YG)	
SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)	
DIMETHICONOL (40 CST) (UNII: 343C7U75XW)	
ALUMINUM OXIDE (UNII: LM26O6933)	
LAURETH-23 (UNII: N72LMW566G)	
METHICONE (20 CST) (UNII: 6777U11MKT)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
PPG-2 MYRISTYL ETHER PROPIONATE (UNII: 88R97D8U8A)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42851-051-01	15 mL in 1 BOTTLE, PUMP		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	01/11/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	01/11/2012	

Labeler - ZO Skin Health, Inc. (826468527)

Establishment

Name	Address	ID/FEI	Business Operations
Lifetech Resources		622559110	MANUFACTURE(42851-154)

Establishment

Name	Address	ID/FEI	Business Operations
PakLab		177711082	MANUFACTURE(42851-154)

Establishment

Name	Address	ID/FEI	Business Operations
Thibiant International		083913913	MANUFACTURE(42851-154)

Establishment

Name	Address	ID/FEI	Business Operations
Owen Biosciences		790003045	MANUFACTURE(42851-154)

Revised: 2/2014

ZO Skin Health, Inc.